

**REMARKS / ARGUMENTS**

***Summary of the Present Invention***

The present application discloses a pressure relief pad for use by persons suffering from or subject to the formation of decubitus ulcers or bedsores. The pad is made from a plurality of layers of resilient material contoured for predetermined areas of the body. The pad provides for the redistribution of pressure around an affected or wounded area allowing the wound to heal faster than without the use of the pad.

In the present application, independent claim 1 has been cancelled. Claim 4, previously dependent from independent claim 1, has been amended to include all the limitations of claim 1 and the limitation originally set forth in claim 4. That is, claim 4 has been amended to require that the pad of the present invention include three elements: a shell composed of a plurality of layers of a resilient material, a platform attached to the shell, and a means for securing the shell to the patient's body. The basis for the amendments to claim 4 can be found in originally filed claims 1 and 4. Remaining claims 5 – 7 depend from now independent claim 4. Claims 2 and 3, which depended from independent claim 1, have been cancelled from the application.

In the present application, claim 8, previously dependent from independent claim 1, has been amended to include all the limitations of claim 1 and the limitation originally set forth in claim 8. That is, claim 8 has been amended to require that the pad of the present invention include three elements: a shell, a platform composed of a plurality of layers of a resilient material attached to the shell, and a means for securing the shell to the patient's body. The basis for the amendments to claim 8 can be found in originally filed claims 1 and 8. Remaining claims 9 – 13 depend from now independent claim 8.

In the present application, independent claims 14 and 25, and their dependent claims 15 – 24 and 26 – 30, respectively, have been cancelled from the application.

***Remarks Regarding Claims Rejected Under 35 USC §102(b) and 35 USC §103(a) in view of U.S. Patent 4,801,291***

The Examiner has rejected claims 1 – 3 and 7 under 35 U.S.C §102(b) as anticipated by Loori (U.S. Patent 4,801,291, "the '291 patent"), and has rejected claims 10 – 13 under 35 U.S.C §103(a) as being obvious in view of Loori (the '291 patent). The '291 patent teaches and claims a topical hyperbaric apparatus comprising a shell with a flexible wall that can conform to a patient's body and form an internal cavity. Independent claims 1, 17, 38, 29, 30 and 33 require

that the apparatus includes a shell having at least one wall providing an external surface and defining a substantially closed internal chamber.

Similar to the present invention, the pad of the '291 patent is intended for use against a body. Further, both pads comprise a flexible shell with an internal cavity and a protuberance for positioning against the patient's body.

However, the pad of the '291 patent is intended to be used to deliver gas into the cavity for therapeutic use, the shell and protuberance function to contain the gas in the cavity. Having a shell or protuberance comprised of separate layers would increase the probability that the gas would leak from the cavity. In contrast, independent claims 4 and 8 of the present application, as amended, require that a portion of the pressure pad be composed of a plurality of layers.

In addition, there is no teaching or suggestion in the '291 patent that the patient could exert a downward pressure on the body part protected by the pad of the '291 patent and have the pad function as intended. Figure 5 of the '291 patent shows the pad applied to a patient. In this figure, which illustrates a "preferred method of application" (column 5, lines 3 – 4), the patient is positioned so as not to exert pressure on the '291 pad. Further, the '291 pad "is conformable to the shape of the surface to which it is applied" (column 5, lines 18 – 19) and is "preferably comprised of polyurethane foam 32 ... characterized by a ... 34-pound indent load deflection ..." Thus, if a patient exerted a downward pressure on the pad, it is expected that the pad would compress, thereby effectively eliminating the cavity into which the gas for therapeutic use is delivered.

By contrast, the pad of the present invention is designed "to provide a means for dispersing the pressure created against the patient's skin or wound when the patient exerts a downward pressure on a particular portion of the body (see present application, page 5, lines 5 – 7). As noted in the Summary section of the present application, although the "pressure relief pad can be applied, for example, over a bedsore to aid the healing of the bedsore", the "pad can also be used over an area that is likely to develop or redevelop a bedsore ..." As is known in the medical arts, bedsores develop when poor or compromised circulation cause blood and other bodily fluids to pool in certain areas of the body – usually at points or regions where a higher degree of pressure is generated between the body and the surface upon which it is resting. In other words, the present invention allows for, and anticipates that, the patient will exert pressure on the pad, and that under these conditions the pad will function precisely as intended.

With respect to claims 10 – 13, the applicant contends that the addition of a strap or belt, and / or the addition of an exudates absorbing material to the device of the '291 patent, would not

make obvious the present development. As noted above, the '291 patent does not teach or suggest that a patient could exert a downward pressure on the body part protected by the pad of the '291 patent and have the pad function as intended, nor that shell or protuberance of the '291 device could be comprised of separate layers and function as intended.

Thus, now independent claims 4 and 8 and their dependent claims 5 – 7 and 9 – 13, respectively, are neither anticipated nor obvious in view of U.S. Patent number 4,801,291. (Independent claim 1, and dependent claims 2 – 3 have been cancelled from the application.)

***Remarks Regarding Claims Rejected Under 35 USC §102(b) in view of U.S. Patent 5,010,878***

The Examiner has rejected claims 1 – 3, 7, 10 and 11 under 35 U.S.C §102(b) as anticipated by Kline et al. (U.S. Patent 5,010,878, "the '878 patent"). The '878 patent teaches and claims an apparatus for supporting a patient's foot such that the patient's toes can be mobilized. The Examiner states that the '878 device recites "a base (22) and a cover (24), both of which are made of resilient foam material. The base (22) is contoured to receive the patient's foot and the cover (24) is fixedly attached opposite to the base (22) by the strap (26)."

In the present application, the pressure relief pad comprises a shell having a base and a side forming a cup contoured to accommodate a specified body part, a platform fixedly attached to the shell base such that the platform opposes the shell, and a means for reversibly securing the shell to said body part. It is the applicant's understanding that the Examiner is relating the base (22) and the cover (24) of the '878 device to the shell and the platform, respectively, of the present invention. If this is the correct interpretation, the applicant contends that, except for each device being made of resilient foam material and being intended for use on a specified body part, the device of the '878 patent and the present invention are distinguishable.

Although both devices do include a "base," the base (22) of the '878 patent is designed to accept a patient's leg, but there is no teaching or suggestion that the base includes any features designed to disperse the pressure created against the patient's skin or wound when the patient exerts a downward pressure on the leg. In contrast, in the present invention, the shell includes a cup contoured to accept a specific body part and a base fixedly attached to a platform. The platform does not serve the function of a cover positioned *opposite* the shell, but rather is fixedly attached to and *opposing* the shell. That is, as described in the '878 patent the cover can be viewed along with the shell as "the other of a pair that are corresponding or complementary in

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position, function, or nature”<sup>1</sup> whereas in the present invention the platform “offers resistance to”<sup>2</sup> the shell.

Thus, now independent claims 4 and 8 and their dependent claims 5 – 7 and 9 – 13, respectively, are not anticipated in view of U.S. Patent number 5,010,878. (Independent claim 1, and dependent claims 2 – 3 have been cancelled from the application.)

***Remarks Regarding Allowable Subject Matter***

Applicant has made note that the Examiner has indicated that Claims 4 – 6, 8 and 9 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all limitations of the base claim and any intervening claims. Applicant believes that, as shown herein, Claims 4 and 8 have been rewritten to independent form as required. Claims 5, 6 and 9 now depend from the amended Claims 4 and 8.

***Remarks Regarding Citations***

Applicant has made note of the prior art recited by the Examiner in the Notice of References Cited.

Applicant respectfully requests that a timely Notice of Allowance be issued in this case.

Respectfully submitted,



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<sup>1</sup> Dictionary definition of “opposite”: Found at [www.merriam-webster.com](http://www.merriam-webster.com), definition number 4.

<sup>2</sup> Dictionary definition of “opposing”: Found at [www.merriam-webster.com](http://www.merriam-webster.com), definition number 3 (see also definition number 3 for “opposite”; and definition 1 and 2 of “opposing”).